



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPPT-2018-0398; FRL-9979-26]**

### **Agency Information Collection Activities; Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances; Emergency Processing Request Submitted to OMB**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA has submitted an amendment to the following information collection request (ICR) to the Office of Management and Budget (OMB) for emergency processing in accordance with the Paperwork Reduction Act (PRA): “Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances” and identified by EPA ICR No. 0574.17 and OMB Control No. 2070-0012. The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is summarized in this document.

**DATES:** EPA requested that OMB approve the emergency processing request on or before June 11, 2018.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0398, is available at <http://www.regulations.gov>. A public version of the docket is available for inspection and copying between 8:30 a.m. and 4:30 p.m., Monday through Friday, excluding federal holidays, at the U.S. Environmental Protection Agency, EPA Docket

Center Reading Room, WJC West Building, Rm. 3334, 1301 Constitution Avenue, NW  
Washington, DC 20004. A reasonable fee may be charged for copying.

**FOR FURTHER INFORMATION CONTACT:** Brandon Mullings, Environmental  
Assistance Division (MC 7408M), Office of Pollution Prevention and Toxics, Environmental  
Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone  
number: (202) 564-4826 email address: *mullings.brandon@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

*Docket:* Supporting documents, including the ICR that explains in detail the information  
collection activities and the related burden and cost estimates that are summarized in this  
document, are available in the docket for this ICR. The docket can be viewed online at  
*<http://www.regulations.gov>* or in person at the EPA Docket Center, West William Jefferson  
Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The telephone number  
for the Docket Center is (202) 566-1744. For additional information about EPA's public docket,  
visit *<http://www.epa.gov/dockets>*.

*ICR status:* EPA is seeking emergency processing of amendments to an existing,  
approved ICR that is currently scheduled to expire on November 30, 2018.

The Agency is issuing additional reporting guidance to help submitters better address the  
recently-amended requirements for new chemicals under the Toxic Substances Control Act  
(TSCA) (15 U.S.C. 2601 *et seq.*). Under the PRA, 44 U.S.C. 3501 *et seq.*, an agency may ask  
OMB to authorize a collection of information if the agency has determined that the collection is  
needed prior to the expiration of time periods established under the PRA if the agency  
determines that the agency cannot reasonably comply with the normal clearance procedures  
under the PRA, because either public harm is reasonably likely to result if normal clearance

procedures are followed, an unanticipated event has occurred, or the use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information or is reasonably likely to cause a statutory or court ordered deadline to be missed.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

*Abstract:* The Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act, immediately effective upon its enactment on June 22, 2016, made significant amendments to TSCA, including imposing a number of new responsibilities related to new chemical reviews. Specifically, TSCA section 5 requires that EPA now assess a new chemical under the “conditions of use,” which is defined as the circumstances, as determined by the Administrator, under which the chemical is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of. TSCA also now requires that EPA make one of five affirmative determinations on the new chemical within the statutory review period. The new determination requirement has resulted in a backlog of section 5 submissions awaiting final action.

In an effort to avoid future delays and backlogs and to assist respondents in preparing a Premanufacture Notice (PMN), Significant New Use Notice (SNUN), or exemption notice (*e.g.*, Low Volume Exemption or LVE) (hereinafter collectively referred to as “notifications”) submissions in a manner that satisfies the amended TSCA section 5 requirements, EPA developed a non-binding guidance document, entitled “*Points to Consider When Preparing*

*TSCA New Chemical Notifications*”. To the extent that respondents are able to take information presented in the Points to Consider document into account prior to preparing and submitting a PMN, SNUN, or exemption notice, EPA also anticipates that more robust submissions will improve the factual bases for determinations on new chemical notices, speed review, and reduce the frequency of interactions with submitters in cases where EPA has questions about the submission. The Points to Consider document is urgently needed for a more timely and efficient new chemical review process. Complying with the normal clearance procedures for approval of the reporting guidance provided in the Points to Consider document could disrupt the collection of information by preventing companies from accessing applicable and helpful EPA guidance with respect to PMNs and SNUNs submitted prior to OMB approval of the ICR and cause harm due to the ensuing delays in marketing new chemical substances because companies do not have access to the guidance.

*Respondents/Affected entities:* Entities potentially affected by this ICR are manufacturers (including importers) and processors of new chemical substances.

*Respondent’s obligation to respond:* Mandatory (15 U.S.C 2604).

*Estimated total number of potential respondents:* 443.

*Frequency of response:* On occasion.

*Estimated total burden:* 117,176 hours (per year). Burden is defined at 5 CFR 1320.3(b).

*Estimated total costs:* \$34,389,692 (per year), includes no annualized capital investment or maintenance and operational costs.

*Changes in the estimates:* There is an increase of 1,379 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This increase reflects the estimated additional time associated with reading the new guidance

document before preparing and submitting a PMN, SNUN, or exemption notice (about 1.4 hours per response). This burden increase is the result of a program change.

**Authority:** 44 U.S.C. 3501 *et seq.*

Dated: June 7, 2018.

Charlotte Bertrand,  
*Acting Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

[FR Doc. 2018-12811 Filed: 6/13/2018 8:45 am; Publication Date: 6/14/2018]